



COLOR PIGMENTS MANUFACTURERS ASSOCIATION, INC.

201-16798

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CPMA
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Mark W. Townsend, Chief
HPV Chemicals Branch
Environmental Protection Agency
Office of Pollution Prevention
and Toxics
1201 Constitution Avenue, NW
Washington, DC 20004

**Re: Response to EPA Comments on the CPMA Test Plan For
3,3' Dichlorobenzidine Dihydrochloride
(CAS No.: 612-83-9)**

Dear Mr. Townsend:

I am writing on behalf of the Color Pigments Manufacturers Association, Inc. ("CPMA") in response to your letter of March 10, 2008 in which you review the Environmental Protection Agency's ("EPA") comments on the CPMA test plan and robust summaries for 3,3' Dichlorobenzidine Dihydrochloride, Chemical Abstract Service No. 612-83-9 ("DCB"). The test plan was submitted to the EPA as part of the voluntary High Production Volume ("HPV") testing program.

The CPMA is an industry trade association representing color pigment companies in Canada, Mexico, and the United States. CPMA represents small, medium, and large color pigments manufacturers throughout Canada, Mexico and the United States, accounting for 95%

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of the production of color pigments in North America. Color pigments are widely used in product compositions of all kinds, including paints, inks, plastics, glass, synthetic fibers, ceramics, colored cement products, textiles, cosmetics, and artists' colors. Color pigment manufacturers located in other countries with sales in Canada, Mexico, and the United States and suppliers of intermediates, other chemicals and other products used by North American manufacturers of color pigments are also members of the Association.

As discussed in more detail below, DCB is a closed system intermediate with no consumer or downstream commercial exposure.

DCB Is Strictly A Chemical Intermediate

EPA comments indicate that more information is needed for EPA to consider DCB a closed system intermediate. DCB is used only as intermediate coupling agents in the manufacture of diarylide pigments. DCB is currently imported for use by no more than six facilities in the United States. Diarylide pigments are produced in water based reactions. The precipitated diarylide pigments that result from these reactions have measured water solubilities well

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below 1 part per million. The reactions that produce diarylide pigments are used in weighted reaction designed to eliminate residual DCB. There is little or no unreacted DCB waste remaining in the final pigment used to color other products.

Exposure To DCB In Commerce

Exposure to DCB in the workplace is absolutely prohibited by applicable Occupational Safety and Health Administration ("OSHA") regulation. As a result, there is no workplace exposure to DCB in use. DCB is handled only in sealed reaction systems within regulated and demarcated work areas. Coupling agents reacted with DCB are always used in excess to ensure that all DCB added to the reaction is consumed in the process. Because diarylide pigments are used by downstream customers in the paint, plastic and ink manufacturing industries, DCB must be eliminated in the production process in order to ensure that no downstream exposure to DCB occurs.

DCB is only imported into the United States. The total number of workers involved in handling DCB indirectly in sealed reaction systems in regulated areas pursuant to existing OSHA regulations is estimated to be no more than 25 in all facilities where DCB is used

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in the United States. DCB is shipped in sealed containers before being consumed completely in the water based reaction processes that produce diarylide pigments.

Inventory Update Data

The aggregated information available from the EPA Inventory Update Rule under the Toxic Substances Control Act is currently in error for DCB. The most recent aggregated data for the year 2006 indicates that between 100 and 999 facilities use DCB and that between 100 and 999 employees are exposed to DCB. These aggregated statistics are incorrect. There are no employees exposed to DCB. Current Federal regulation forbids any such exposure. The total number of employees entering regulated areas where DCB reactions are conducted is no more than 25. There are no more than six facilities using DCB in the manufacture of diarylide pigments.

Reaction Scheme

DCB is completely consumed to produce diarylide pigments. The following reaction schemes are provided as examples:

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1.	DCB --> Acetoacetanilide C.I. Pigment Yellow 12
2.	DCB --> 4'chloro 2'5' dimethoxyacetoactanilide C.I. Pigment Yellow 83
3.	DCB --> AcetoAcetorthotoluidide C.I. Pigment Yellow 14

DCB is used in weighted reactions designed to react all present DCB. It is not possible for significant amounts of DCB to survive these coupling reactions and remain intact in the final pigments. Any traces of un-reacted DCB present in the reaction process used to produce diarylide pigments would be contained in the water used as the reaction media. DCB is readily removed from wastewater by oxidation bleaching.

Diarylide pigments are used in printing inks, paints and some plastics. There is no further exposure to DCB in downstream commercial uses of finished diarylide pigments or consumer applications and products. Diarylide pigments are encapsulated in the resins which make up inks, paints or plastics.

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There Are No Other Known Uses Of DCB

The OECD SIDS Initial Assessment Report ("SIAR") for the diarylide pigments and our research and discussions with importers, manufacturers and users of DCB indicate that DCB is used only as intermediate reactant in the manufacture of diarylide pigments.

Additional Animal Studies

Regarding EPA's request for additional animal studies for DCB the additional information provided above should be more than sufficient to categorize this compound as a closed system intermediate. We disagree strongly with the assumption that additional studies will provide useful information commensurate with the cost. DCB has been thoroughly tested in both the environment and in various species. DCB is strictly regulated as a known human carcinogen. There is, as a result no benefit to further toxicological testing for DCB, since exposure to a toxic dose, at any level, is prohibited under current law. CPMA utilized the considerable number of references and study descriptions compiled by the Agency for Toxic Substances and Disease Registry

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("ATSDR") for the Chemical profile for DCB. Given the extremely limited use of DCB and the prohibition on any exposure to DCB, we must question the utility and need for additional studies or descriptions for this well understood intermediate. If, after review of this information, EPA still requires additional data for DCB, the CPMA will undertake to locate and summarize additional studies for DCB.

DCB is also imported and used by pigment manufacturers in Europe in large quantities. As a result, DCB will be the subject of review and testing, as necessary, under the European Union Registration Evaluation and Authorization of Chemicals ("REACH") regulation. The review, and any additional testing, will cover the data points requested by EPA. This larger group of international producers and users will be required to participate in the REACH program in order to continue to sell and use 2b acid and C amine in Europe. Therefore, since the remaining data points will be addressed by a larger group of manufacturers and users in the REACH program, CPMA members should not be burdened with the obligation to independently fund these studies twice. We will monitor progress of this substance in the REACH program and summarize the data for EPA when any necessary studies are complete.

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DCB has limited use in no more than six facilities in the United States and no exposure to DCB is permitted in the United States.

CPMA makes no commitment with respect to the intermediates represented by this letter and the enclosed data or any guideline or requirement established pursuant to the voluntary HPV program or otherwise. Furthermore, CPMA reserves the right to defer the review of this chemical if it or an analog has been the subject of another undertaking in any EPA program or other similar international programs.

CPMA further reserves the right to withdraw this Test Plan should the HPV program, when and if finalized, prove to be different from that understood, from time to time, by CPMA. Since all of the pigments and intermediates represented by CPMA have been used in international commerce for many years, there is extensive data available from a variety of published and unpublished sources.

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In conclusion, even though these intermediates are no longer HPV substances with production or import in excess of one million pounds per year, sufficient information has been identified and incorporated in the enclosed to allow for completion of the EPA voluntary HPV program for these insoluble intermediates without further redundant and unnecessary testing.

Thank you for your attention. Please call if there are any questions or comments.

Sincerely,

J. Lawrence Robinson
President

ENCLOSURE